UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

TAMMY ASHWORTH

Plaintiff

v. **Civil Action No.: 2:05-0139**

ALBERS MEDICAL, INC., a/k/a Albers Medical Distributors, Inc., MED-PRO INC., PFIZER, INC., and H.D. SMITH WHOLESALE DRUG COMPANY

Defendants

UNITED STATES OF AMERICA

Intervenor

MEMORANDUM ORDER AND OPINION

Pending before the court is the motion of defendant Pfizer, Inc., filed February 28, 2005, seeking dismissal of the claims of plaintiff Tammy Ashworth pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

I.

A. Purchases.

This action arises from two prescription purchases made by plaintiff from a Rite Aid pharmacy located in Big Chimney,

West Virginia. Compl. at ¶¶ 23-24. Plaintiff, diagnosed with high cholesterol, had been prescribed LIPITOR, a prescription drug with the active ingredient atorvastatin calcium. Id. at ¶¶ 10-11. LIPITOR is patented, trademarked and manufactured by Pfizer - a nationwide pharmaceutical company. Id. at ¶ 10.

Twice, on April 24, 2003 and May 22, 2003, she purchased 30 tablets purporting to be 10mg Lipitor. Id. at ¶¶ 23-24. She states that "[i]nstead of receiving the LIPITOR™ for which she paid, she received, upon information and belief, counterfeit LIPITOR™ pills that had dubious medicinal value which did not provide any treatment for her high cholesterol." Id. at ¶ 23. Although the complaint does not so explicitly state, it may be inferred that she ingested the counterfeit tablets from approximately April 24, 2003, to June 9, 2003. Id. at ¶¶ 25 & 29-31. On June 9, 2003, the plaintiff received a letter from Rite Aid dated May 31, 2003, informing her of an announcement by the Food and Drug Administration ("FDA") that Albers Medical Distributors ("Albers") had voluntarily recalled certain lots of 10mg LIPITOR and requesting that consumers return any unused tablets purchased between April 3 and May 23, 2003. Id. at ¶ 26.

B. Counterfeit Operation.

The recall resulted from the discovery of a sophisticated counterfeiting operation engaged in the manufacture of counterfeit LIPITOR and the illegal diversion of LIPITOR that was intended for foreign markets and not approved for sale in the United States.[1] Plaintiff contends that counterfeit LIPITOR was distributed by defendants Albers Medical, Inc. ("Albers"), and H.D. Smith Wholesale Drug Company ("H.D. Smith"). Id. at ¶ 12. She further contends that Rite Aid has alleged in separate litigation that it purchased from H.D. Smith bottles of LIPITOR with a lot number which the FDA subsequently identified as containing counterfeits.[2] Id. at ¶¶ 17-18. The counterfeit LIPITOR was repackaged by Med-Pro, Inc. Id. at ¶ 19. With respect to Albers, plaintiff states that:

> Albers is a national distributor of prescription and non-prescription pharmaceutical products and medical supplies that is engaged in the business of repackaging, distribution and sale of pharmaceutical products, including the counterfeit Lipitor™ products.

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[1]The details of the counterfeiting operation as presented to the court are more thoroughly summarized in the court's order of July 25, 2005, concerning plaintiff's motion to remand.

[2]Plaintiff has alleged that the FDA issued two separate notices each advising of the recall of three distinct lots repackaged and labeled by Med Pro, Inc. Plaintiff does not allege the particular lot or lots that were sold by Albers to H.D. Smith and resold by H.D. Smith to Rite Aid.

> Albers has been repeatedly cited by state regulators for buying drugs from unlicensed dealers and otherwise violating rules designed to prevent counterfeit drugs from reaching consumers.

Id. at ¶ 3.

C. Allegations against Pfizer.

Plaintiff mentions Pfizer specifically in the following allegations:

> 6. Defendant Pfizer Inc. is a corporation in good standing organized under the laws of the State of Delaware with a principal place of business at 235 East 42nd Street, New York, New York. Pfizer is a nationwide public pharmaceutical company is [sic] engaged in the business of manufacturing and distributing pharmaceutical products, including LIPITOR™ product. Pfizer had and continues to have significant contacts with the state of West Virginia and that it manufactured and distributed bottles of LIPITOR™ for shipment to West Virginia for sale to West Virginia residents. Further, at all relevant times hereto, Pfizer had exclusive control of the patents, trademarks, manufacturing, labeling, packaging, re-packaging, distribution, and sale of Lipitor™.
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> . . . .
>
> 10. The pharmaceutical product LIPITOR™ is exclusively manufactured by Pfizer and/or Pfizer Ireland Pharmaceuticals and, pursuant to the approval of the U.S. Food & Drug Administration ("FDA"), distributed by Pfizer, Inc. LIPITOR™ is used in the treatment of cardiovascular disorders and cholesterol reduction and contains the active ingredient atorvastatin calcium. LIPITOR™ is the most widely prescribed cholesterol-lowering drug in the United States, and is a high cost prescription drug. It has been prescribed to over 18 million Americans to aid in the lowering [of] cholesterol levels, and is taken by 11 million

> **Americans daily to help their cholesterol levels, upon information and belief.**
>
> **. . . .**
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> **20. . . . Defendants' counterfeit LIPITOR™ products have been distributed and sold to the trade and to consumers, who consume them under the false belief that they were genuine LIPITOR™ products manufactured by Pfizer or manufactured pursuant to both Pfizer and the FDA's quality control standards.**
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> **. . . .**
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> **21. Defendants' distribution, repackaging, and sale of counterfeit LIPITOR™ products and possibly other drugs have deceived purchasers in the consuming public. Actual and potential consumers in West Virginia and throughout the United States, upon encountering defendants' products bearing counterfeits, reproductions, copies or other colorable imitations of LIPITOR™ are likely to mistakenly believe that these products are approved by the FDA and Pfizer.**
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> **50. Defendants were negligent and breached their duties by one or more of the following negligent acts and/or omissions:**
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> **. . . .**
>
> **e. Failing to advise other defendants, the FDA, and the general public that the source of LIPITOR™ products was not Pfizer, or an authorized distributor of Pfizer.**

Id. at ¶¶ 6, 10, 20-21 & 50.

In addition to these specific allegations, plaintiff alleges that the "Defendants were all in the chain of manufacturing and distribution of counterfeit LIPITOR™" and "together they manufactured, licensed the manufacture, sold, marketed, advertised, and/or distributed the counterfeit LIPITOR™

in the course of their respective business [sic]." Id. at ¶¶ 34 & 38. Plaintiff contends that the defendants failed to "institute reasonable safeguards against counterfeit LIPITOR™ products entering the stream of commerce" and that the risks of counterfeit proliferation were well known to them. Id. at ¶ 50f.

D. Complaint.

On or about January 18, 2005, plaintiff filed a ten-count complaint in the Circuit Court of Kanawha County, West Virginia, against defendants Albers, Med-Pro, Inc., Pfizer, Rite Aid and H.D. Smith. Count I alleges that the "[d]efendants" were engaged in the manufacture, distribution and sale of counterfeit LIPITOR and asserts that the counterfeits were unreasonably dangerous and defective for their intended use. It is also alleged that defendants failed to provide adequate warnings. Count II asserts that the defendants were negligent inasmuch as they failed to exercise reasonable care to assure that counterfeit LIPITOR would not be allowed to enter the chain of distribution and be sold to the general public.

Count III states that defendants expressly warranted that LIPITOR was safe and effective for the uses intended and that the counterfeits sold did not conform to such

representations. Count IV contends that the counterfeits breached the implied warranties of merchantability and fitness for a particular use. Count V alleges that the defendants defrauded plaintiff inasmuch as she relied upon their representation that LIPITOR was safe and effective, necessarily implying that the product purchased was not counterfeit. Count VI asserts that defendants engaged in a civil conspiracy to defraud the public, including the plaintiff. Count VII states that the defendants' actions in marketing and selling counterfeit LIPITOR violated W. Va. Code §§ 46A-6-101, et seq. Count VIII asserts that Rite Aid of West Virginia, Inc., violated W. Va. Code § 16-29-1 by failing to provide plaintiff's medical records in response to an authorized written request. Count IX asserts a claim for punitive damages and Count XI asserts a claim for intentional infliction of emotional distress against all defendants. There is no Count X.

The court, by order dated July 25, 2005, dismissed Rite Aid as to Counts I-VII, IX & XI. The court also severed Count VIII which was brought solely against Rite Aid and remanded that claim to the Circuit Court of Kanawha County, West Virginia.

Pfizer seeks dismissal of the plaintiff's claims, contending that it was not responsible for the manufacture,

distribution and sale of counterfeit LIPITOR and it thus may not be held legally responsible for any strict liability or warranty claims nor for claims based on violations of W. Va. Code §§ 46A-6-101, et seq. Pfizer asserts that plaintiff's fraud claim is not pled with the requisite specificity and that Pfizer was not part of the counterfeit conspiracy. Pfizer further contends that it was under no legal duty either to assure that counterfeit LIPITOR would not be allowed to enter the chain of distribution or to assure that it not be sold to the general public.

In response, plaintiff contends that under West Virginia law the existence of a legal duty is dependent on whether the risk of harm was foreseeable. Plaintiff asserts that Pfizer had a duty to the plaintiff "to safeguard the chain of distribution to combat the dangers of counterfeiting." Pl.'s Resp. at p. 9. Plaintiff, however, does not respond to the contention that Pfizer was not a participant in the counterfeiting scheme or in the chain of distribution for the counterfeit LIPITOR. Indeed, the complaint specifically states that Pfizer was not the source of the counterfeit LIPITOR. Compl. at ¶ 50e.

II.

A motion to dismiss for failure to state a claim should not be granted "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46 (1957). In considering a motion to dismiss, the court should accept as true all well-pleaded allegations and should view the complaint in the light most favorable to the plaintiff. Mylan Laboratories, Inc. v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993), cert. denied, 510 U.S. 1197 (1994) (citations omitted); see also Brooks v. City of Winston-Salem, 85 F.3d 178, 181 (4th Cir. 1996). The purpose of a motion to dismiss is to test the legal sufficiency of the plaintiff's complaint. See District 28, United Mine Workers of America, Inc. v. Wellmore Coal Co., 609 F.2d 1083, 1085-86 (4th Cir. 1979). A court should not grant a Rule 12(b)(6) motion unless "'it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" H.J. Inc. v. Northwestern Bell Tel. Co., 492 U.S. 229, 249- 50, 109 S.Ct. 2893, 106 L.Ed.2d 195 (1989) (quoting Hishon v. King & Spalding, 467 U.S. 69, 73, 104 S.Ct. 2229, 81 L.Ed.2d 59 (1984)).

Inasmuch as a motion to dismiss tests the legal

sufficiency of the complaint, the focus of the court's inquiry is the complaint. However, in determining a motion under Fed. R. Civ. P. 12(b)(6), a court may consider extraneous materials only if such materials are "integral to and explicitly relied upon in the complaint." Phillips v. LCI International, Inc., 190 F.3d 609, 618 (4th Cir. 1999).

III.

A. Counts I, III, IV and VII: Strict Liability, Breach of Warranty, and Violations of W. Va. Code §§ 46A-6-101, et seq.

Under West Virginia law, a manufacturer may be held strictly liable if it places a product that has a design or structural defect into the stream of commerce and that defect is the proximate cause of an injury. Morningstar v. Black & Decker Mfg. Co., 253 S.E.2d 666, 682 (W. Va. 1979). The plaintiff must show "that the product was defective when it left the manufacturer and that the defect proximately caused the plaintiff's injury." Id. at 680.

Section 46A-6-106 of the West Virginia Consumer Credit and Protection Act, W. Va. Code §§ 46A-6-101 et seq., establishes a cause of action for consumers who purchase goods and services and are injured as the result of any practice that is deemed

unlawful pursuant to the other provisions of that article. Section 46A-6-108 also abolishes the requirement of privity with respect to warranty claims. The consumer thus may pursue warranty claims against the manufacturer.

The basic prerequisite necessary to have standing for any of these claims is the purchase by a person or consumer of a product placed into the chain of distribution by the manufacturer. Plaintiff thus need only show that Pfizer was either the manufacturer of, or part of the chain of distribution for, the counterfeit LIPITOR.

Plaintiff specifically claims that her injuries were proximately related to two purchases of counterfeit LIPITOR tablets. Unlike plaintiff's allegations against Albers, Med Pro, Inc., and H.D. Smith, there are no specific allegations linking Pfizer, Inc., to the manufacture, distribution or sale of the counterfeit LIPITOR. Rather, plaintiff alleges only that Pfizer is the manufacturer and trademark and patent holder of LIPITOR.

Although plaintiff does allege that "[d]efendants were situated in the chain of commerce and together they manufactured, licensed the manufacture, sold, marketed, advertised, and/or distributed the counterfeit LIPITOR™ in the course of their

respective business," her specific allegations as to Pfizer are inconsistent with the position that Pfizer participated in the counterfeiting scheme. Moreover, to conclude that Pfizer would participate in that scheme defies logic inasmuch as the scheme serves only to diminish Pifzer's profits and dilute Pfizer's trademark and patent rights. Plaintiff, for her part, has not opposed Pfizer's assertion that it did not participate in the counterfeit scheme and has not otherwise suggested that Pfizer was within the chain of distribution for the counterfeits. The court finds Pfizer is entitled to dismissal of Counts I, III, IV and VII.

B. Counts V, VI, IX and XI: Fraud, Conspiracy, Punitive Damages and Intentional Infliction of Emotional Distress.

Pfizer contends that plaintiff has not pled fraud with the requisite specificity. Rule 9(b) of the Federal Rules of Civil Procedure provides that:

> In all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally.

Fed. R. Civ. P. 9(b). The circumstances to be pled with particularity are the "'time, place, and contents of the false representation, as well as the identity of the person making the

misrepresentation and what he obtained thereby.'" Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999) (citing 5 Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1297, at 590 (2d ed. 1990)). Consistent with the second sentence of Rule 9(b), a plaintiff need only set forth conclusional allegations as to a defendant's intent to deceive. Id. The Fourth Circuit has stated that:

> Rule 9(b) has four purposes:
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> > First, the rule ensures that the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of ... Second, Rule 9(b) exists to protect defendants from frivolous suits. A third reason for the rule is to eliminate fraud actions in which all the facts are learned after discovery. Finally, Rule 9(b) protects defendants from harm to their goodwill and reputation.
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> United States ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Blue Cross Blue Shield of Georgia, Inc., 755 F. Supp. 1055, 1056-57 (S.D. Ga. 1990). A court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts.

Id.

Under West Virginia law, "[t]he essential elements in an action for fraud are: '(1) that the act claimed to be fraudulent was the act of the defendant or induced by him; (2)

that it was material and false; that plaintiff relied upon it and was justified under the circumstances in relying upon it; and (3) that he was damaged because he relied upon it.'" Syl Pt. 1, Lengyel v. Lint, 280 S.E.2d 66 (W. Va. 1981) (citing Horton v. Tyree, 104 W.Va. 238, 242, 139 S.E. 737 (1927)). "Actual fraud is intentional, and consists of intentional deception to induce another to part with property or to surrender some legal right, and which accomplishes the end designed." Stanley v. Sewell Coal Co., 285 S.E.2d 679, 683 (W. Va. 1981).

Plaintiff's fraud claim is pled as follows:

> 60. Plaintiffs [sic] incorporates, repeats, and realleges each and every allegation contained in the foregoing paragraphs of this Complaint as thought [sic] fully set forth herein.
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> 61. Defendants represented to the general public, and Tammy Ashworth specifically, that LIPITOR™ was safe and effective.
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> 62. Defendants represented to the general public, and Tammy Ashworth specifically, that LIPITOR™ was safe and effective for use to treat high cholesterol, and by implication, that the LIPITOR™ product purchased was not counterfeit, all of which constituted gross misrepresentation of material fact upon which Ms. Ashworth relied to her detriment.
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> 63. As a result, Plaintiff sustained and incurred injuries and damages.

Compl.

Plaintiff has not stated a claim of fraud against

Pfizer. Plaintiff has not pled the time, manner, and content of any representation made by Pfizer to her. Even assuming that plaintiff's allegations refer to Pfizer's general advertising of its LIPITOR product, plaintiff's claim still fails. Any such representation made by Pfizer as to LIPITOR pertains to a product which plaintiff does not specifically allege she bought. Pfizer's advertising was intended to have plaintiff purchase LIPITOR, not counterfeits. Additionally, plaintiff has not opposed Pfizer's position that no claim in fraud has been pled against it. For these reasons, the court finds that Count V should be dismissed as to Pfizer.

Plaintiff has alleged a conspiracy claim stating "defendant" [sic] developed a scheme to unlawfully defraud the consuming public, including Tammy Ashworth, and to violate West Virginia's consumer protection laws, by claiming that its product LIPITOR™ was safe and effective." Id. at p. 65. She has further alleged that the defendants intentionally inflicted emotional distress upon her. No allegations have been made and no inference can be drawn from those factual allegations set forth that Pfizer joined a conspiracy with the remaining defendants or otherwise acted with intentionality. The court finds that Pfizer is entitled to dismissal of Counts VI and XI.

Inasmuch as plaintiff has not stated a claim in either fraud, intentional infliction of emotional distress or any other cause of action giving rise to the availability of punitive damages against Pfizer, Count IX, the punitive damages claim, is also subject to dismissal.

C. Count II: Negligence.

Count II asserts negligent failure to exercise reasonable care to assure that counterfeit LIPITOR products were not allowed to enter the chain of distribution and be sold to the general public. In West Virginia to establish a prima facie case of negligence, a plaintiff must show the defendant has either acted or omitted to act in breach of a standard of care or duty owed to the plaintiff. Syl. Pt. 3, Aikens v. Debow, 542 S.E.2d 576 (W. Va. 2001). "The determination of whether a defendant in a particular case owes a duty to the plaintiff is not a factual question for the jury; rather the determination of whether a plaintiff is owed a duty of care by a defendant must be rendered by the court as a matter of law." Id. at Syl. Pt. 4. As one court has noted:

> Duty, as a term of art in the law of torts, is not easily defined. It is bound up with notions of public policy and the realities of everyday life; it is in essence, a tool by which society places controllable limits on actions and inactions for which parties may

> be answerable in damages. . . . [T]he standard of conduct to which one must adhere "is the necessary complement of duty;" duty and conduct are 'correlative, and one cannot exist without the other."

Elsroth v. Johnson & Johnson, 700 F. Supp. 151, 156 (S.D.N.Y. 1988) (quoting W. Prosser, Handbook of the Law of Torts § 53, at 324 (4th ed. 1971)). Absent a legal duty, there is no cause for negligence. Reed v. Phillips, 452 S.E.2d 708, 712 (W. Va. 1994).

The existence of a duty is tied to the forseeability that a harm might result in the absence of exercise of due care. Syl. Pt. 3, Sewell v. Gregory, 371 S.E.2d 82 (W. Va. 1988). Foreseeability generally raises questions of law and fact. Syl. Pt. 11, Strahin v. Cleavenger, 603 S.E.2d 197 (W. Va. 2004). In Strahin, the court stated that:

> A court's overall purpose in its consideration of foreseeability in conjunction with the duty owed is to discern in general terms whether the type of conduct at issue is sufficiently likely to result in the kind of harm experienced based on the evidence presented. If the court determines that disputed facts related to foreseeability, viewed in the light most favorable to the plaintiff, are sufficient to support foreseeability, resolution of the disputed facts is a jury question.

Id.

With respect to forseeability in this action, 21 U.S.C. § 321(g)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., defines a "counterfeit drug" as follows:

> a drug, which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor.

21 U.S.C. § 321(g)(2). Sections 331 and 333 criminalize the knowing manufacture, distribution and sale of counterfeit drugs as well as the illegitimate diversion of drugs. Inasmuch as this action concerns plaintiff's purchase and consumption of counterfeit drugs, the harm ultimately encountered by plaintiff is the proximate result of a criminal violation or violations of the Food, Drug and Cosmetic Act somewhere in the chain of distribution.[3]

Typically, a person "does not have a duty to protect others from the deliberate criminal conduct of third parties." Miller v. Whitworth, 455 S.E.2d 821, 825 (W. Va. 1995). The absence of a duty to protect another person from third party criminal acts is grounded in the presumption that ordinarily persons will not violate the criminal laws. Id. Another

[3]There are individuals, not parties to this action, who have already been found criminally responsible for their participation in the counterfeiting scheme.

consideration for this rule is the social and economic consequences of placing a duty upon a person which is otherwise exclusively relegated to the government and its law enforcement agencies. Id. However, the court in Miller did recognize that under certain circumstances a person may have a duty to protect others from the criminal activity of a third party, delineating the situations in which such duty arises as follows:

> (1) when a person has a special relationship which gives rise to a duty to protect another person from intentional misconduct or (2) when the person's affirmative actions or omissions have exposed another to a foreseeable high risk of harm from the intentional misconduct.

Id. The West Virginia Supreme Court has not considered the scope of a duty, if any, owed by manufacturers to combat counterfeit products.

Plaintiff has not identified any statute, rule or regulation promulgated by the State of West Virginia or the federal government which Pfizer may be said to have violated and, although plaintiff has alleged that she had a prescription for LIPITOR, she does not allege that she purchased LIPITOR. Indeed, plaintiff specifically alleges that her injuries were proximately related to her purchase of counterfeit LIPITOR. Pfizer is not responsible for the manufacture, distribution or sale of the counterfeits and may not be held legally responsible for any

claims arising from the physical manufacture, distribution and sale of the counterfeit products.

Nevertheless, plaintiff does identify Pfizer as the proper manufacturer of LIPITOR. She contends in Count II that, despite the well known risks of counterfeiting, "defendants" failed to institute reasonable safeguards to prevent counterfeit products from reaching the market. It appears that she seeks to impose liability on Pfizer simply as the manufacturer of the legitimate product.

As a preliminary matter, plaintiff contends that inasmuch as the existence of a duty is dependent on foreseeability as announced in Strahin, the court's analysis will always require a determination of mixed questions of fact and law and thus is never susceptible to resolution by a 12(b)(6) motion. However, Strahin does not eviscerate the role of the court as a gatekeeper in a negligence action. Inasmuch as it is conceivable that in certain circumstances a duty may not arise regardless of the facts alleged, the court finds plaintiff's proposition is without merit. A negligence claim, like any other claim, is susceptible to legal challenge by a Rule 12(b)(6) motion.

Plaintiff claims that Pfizer had a duty to ensure that

adequate safeguards were in place to combat counterfeiting. Plaintiff appears to advance two theories with respect to the fulfillment of this duty. First, plaintiff suggests that Pfizer may have designed a more counterfeit resistant product and packaging. Second, plaintiff contends that Pfizer may have exercised more control over its distributors.

As to plaintiff's first theory, while this is a counterfeiting rather than a tampering case, courts have found that a manufacturer does not have a duty to anticipate and frustrate criminal tampering.[4] "'[T]amper-proof packaging is not possible.'" Elsroth, 700 F. Supp. at 161 (quoting 47 Fed. Reg. 50,422, 50,444 (Nov. 5. 1982)); see also id. at 164 ("there

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[4]Plaintiff has not cited any case that extends such liability to manufacturers. Strahin, the case relied upon by plaintiff, concerns claims based on premises liability. In Strahin, the facts established that the defendant landowner was aware of a particularized and realized danger from an identifiable third party because of the defendant's relationship with the third party's ex-girlfriend. 603 S.E.2d at 209. The defendant was also aware of violent acts against his property which he had reason to believe had been caused by that third party. Id. The court sustained a verdict finding the defendant liable to an invitee for injuries sustained when the known dangerous third party shot the invitee with a rifle inasmuch as the defendant, under the circumstances, had exposed his invitee to a high risk of harm from a known source. Id.

The generalized risk of counterfeiting pervades every transaction in goods. Here, plaintiff has merely alleged that Pfizer manufactured a product susceptible to counterfeiting. This is not the particularized knowledge noted in Strahin.

exists no common-law duty requiring drug manufacturers to design their products in such a way as to anticipate and frustrate criminal tampering."); Fagan v. Amerisourcebergen Corp., 356 F. Supp.2d 198, 207 (E.D.N.Y. 2004) ("since no packaging is tamper-proof, it cannot be said that alternative packaging would have prevented the counterfeit."); Id. at 207 ("a manufacturer does not have a duty to anticipate and prevent criminal conduct by third parties, or to design its product in such a way as to anticipate and frustrate criminal tampering."); see also Port Authority of New York and New Jersey v. Arcadian Corp., 189 F.3d 305, 316 (3rd Cir. 1999) (holding that no duty existed under the common law of either New York or New Jersey which required fertilizer manufacturers to render their products non-detonable). Elsroth, 700 F. Supp. at 164.

In Arcadian, the Third Circuit affirmed a district court's dismissal of a building owner's claims against fertilizer manufacturers arising from the 1993 bombing of the World Trade Center. The court found that no duty existed even though plaintiff had alleged that the manufacturers' products were capable of being rendered non-detonable through a readily known method to the industry and that the manufacturers knew or should have known that their products had previously been incorporated

in terrorist devices. In Elsroth, a case involving a third-party adulteration of a product, the court stated that:

> The notion that manufacturers should nonetheless be forced to write-off the consequences of determined criminal tampering by third parties as a cost of doing business would be an unprecedented extension of the common law. Automobile manufacturers are not liable to those burglarized when automobiles are used to effectuate burglaries; telephone companies are not liable to those defrauded when the telephone lines are used to perpetrate fraudulent schemes; and handgun manufacturers are not liable to those injured when handguns are used to inflict criminal harm.

700 F. Supp. at 164.

It may be suggested that a manufacturer may discharge the duty plaintiff seeks to impose by implementing a general pre-emptive warning on its labels and advertising materials warning that its products are, as any product in the marketplace, susceptible to imitation. Even if a general pre-emptive warning had been given that the product was susceptible to imitation, that warning would not ensure that the specific harm – the purchase and consumption of counterfeits – would be thwarted. Elsroth, 700 F. Supp. at 166 ("this tragedy [the consumption of cyanide laced Tylenol] would have occurred whether or not there had been a warning that the packaging was not tamper-proof, and the claim must fail."); see also Pl.'s Resp at Ex. D, p. i (February 18, 2004, report of FDA titled "Combating Counterfeit

Drugs: A Report of the Food and Drug Administration" ("FDA Report")) ("[b]ecause the capabilities of counterfeiters continue to evolve rapidly, there is no single 'magic bullet' technology that provides any long-term assurance of drug security.").

It is evident from plaintiff's allegations that, to the extent she can prove she is a victim of the counterfeit scheme, she was victimized by a sophisticated international criminal operation capable of mass producing tablets that were colorable imitations of LIPITOR. That enterprise managed to successfully penetrate the highly regulated and relatively secure United States prescription drug market. Pfizer's only link to this action is its successful product which the criminal operation chose to counterfeit. Even if Pfizer had implemented the strictest of available counterfeit measures to its product and product line, there is no assurance that the harm complained of would not have resulted.[5] Pfizer, by virtue of its status as the

[5]Plaintiff states that there are a litany of anti-counterfeiting measures, identified in the FDA Report, that could have been employed by Pfizer. Pl.'s Resp. at Ex. D. Some of the identified measures such as unit packaging were not thought to impose a sufficient cost deterrent. Id. at pp. 3-4. Other measures such as electronic tracking and tracing were not available for use. Id. at pp. 9-11. Still other measures such as authentication technologies were available but are still capable of being reproduced by counterfeiters and require both reduction of existing regulatory hurdles and development of FDA guidelines concerning implementation. Id. at pp. 5-7. Of

manufacturer of the product that was counterfeited, does not become a marketplace insurer. The court finds that there exists no duty on the manufacturer at common law to ensure that its products are counterfeit-proof.

As to her second theory, plaintiff contends that Pfizer should have regulated its authorized distributor to prevent the infiltration of counterfeits. This argument is predicated on certain proposed, but never implemented, FDA regulations related to pedigree papers. Even if those rules had been adopted, at least one court faced with claims arising from the sale of counterfeit LIPITOR has noted that Albers did obtain written pedigree papers, although apparently unreliable, in connection with its purchase of the counterfeits.[6] Arons v. Rite Aid Corp., 2005 WL 975462 at *2 (March 23, 2005, N.J. Super. Ct. Law Div.). Plaintiff has identified no existing law, regulation or rule

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course, no measure or combination of measures is counterfeit-proof. Id. at p. i.

[6]The Holt Affidavit, previously cited to the court in this case by plaintiff and relied on by the court in granting partially the motion to dismiss by Rite Aid, indicates that the counterfeit LIPITOR was accompanied by a pedigree paper which referenced certain transactions that never happened. Pl.'s Reply Mot. Remand at Ex. E, ¶ 3. The FDA Report notes that pedigree papers are susceptible to falsification. Pl.'s Resp. at Ex. D, p. ii. It would appear that here the requirement of a pedigree paper would not have deterred marketplace penetration by this particular counterfeiting operation.

placing a duty on Pfizer to police its distributors. The court finds that Pfizer had no legal duty, at common law, to do so.

Although the complaint does not specifically so state, Count II could perhaps be read broadly to allege a negligent failure on the part of Pfizer, once it became aware that counterfeit LIPITOR had entered the marketplace, to timely warn the general public, including the plaintiff, of the presence of counterfeit LIPITOR and issue a recall accordingly. Pfizer alleges in its motion to dismiss the lack of a recognized duty that can serve as a predicate for plaintiff's claim of negligence against it; and asserts in its supporting brief that no state or federal statute or regulation imposes any duty upon it to monitor the marketplace or take any action with respect to counterfeits and that it has no duty at common law or otherwise to protect the public from the criminal acts of third parties distributing counterfeit LIPITOR. Def.'s Mem. Supp. Mot. Dismiss at pp. 7-8. Plaintiff, however, makes no mention in its responding brief of such a claim as that outlined above by the court and cites no case law establishing the existence of a duty that would support it. Moreover, plaintiff has furnished the statement of Pfizer's John Theriault that Pfizer notified the FDA on April 29, 2003, of the counterfeit LIPITOR that had come to its attention, which

notification may have played a part in the first announcement of the FDA on May 23, 2003, that Albers was recalling three identified lots of 10 mg LIPITOR. Pl.'s Response at Ex. B, p. 4 (April 5, 2004, testimony of Theriault, Vice President of Pfizer's Global Security, before the Drug Importation Task Force).

The court concludes that Count II should also be dismissed as to Pfizer.

IV.

For the reasons set forth, it is accordingly ORDERED that Pfizer's motion to dismiss be, and it hereby is, granted.

The Clerk is directed to forward copies of this written opinion to all counsel of record.

DATED: August 23, 2005

John T. Copenhaver, Jr.
United States District Judge